

Document: OECD GUIDELINE FOR THE TESTING OF CHEMICALS DRAFT PROPOSAL FOR A NEW TEST
GUIDELINE Skin Sensitisation: Local Lymph Node Assay: BrdU-ELISA

Send Comments to: Patric Amcoff

Comments due by: January 27, 2010

Comment Number	Guideline Document Paragraph	Comments	Proposed Action
1	1	<p>The three published papers on the LLNA by NICEATM and ICCVAM should be included as additional references:</p> <p>Dean JH, Twerdok LE, Tice RR, Sailstad DM, Hattan DG, Stokes WS. 2001. ICCVAM evaluation of the murine local lymph node assay: II. Conclusions and recommendations of an independent scientific peer review panel. <i>Regulatory Toxicology and Pharmacology</i> 34(3): 258-273.</p> <p>Haneke KE, Tice RR, Carson BL, Margolin BH, Stokes WS. 2001. ICCVAM evaluation of the murine local lymph node assay: III. Data analyses completed by the national toxicology program interagency center for the evaluation of alternative toxicological methods. <i>Regulatory Toxicology and Pharmacology</i> 34(3): 274-286.</p> <p>Sailstad DM, Hattan D, Hill RN, Stokes WS. 2001. ICCVAM evaluation of the murine local lymph node assay: I. The ICCVAM review process. <i>Regulatory Toxicology and Pharmacology</i> 34(3): 249-257.</p>	References will be added after the following sentence: <i>The details of the validation of the LLNA and a review of the associated work have been published.</i>
2	25	If adopted, the rLLNA: BrdU-ELISA, as with Guideline 429 could be used in most cases where a simple yes or no answer is needed.	No change requested. The commenter is stating the utility of the rLLNA: BrdU-ELISA, which is already noted in the text.

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3	34	Now that "should" has been changed to "could" in line 333, the phrase "an evaluation of the dose-response relationship as well as" should be returned to the text. Without it, the linear regression and Williams's [note corrected spelling] allusions make no sense, and M. Woolhiser's concern ¹ is no longer pertinent with "could" instead of "should."	Text will be changed to (addition in bold): <i>Any statistical assessment could include an evaluation of the dose-response relationship as well as suitably adjusted comparisons of test groups (e.g. pair-wise dosed group versus concurrent solvent/vehicle control comparisons).</i>

¹ M. Woolhiser's comment on December 11, 2009 to OECD expert consultation group: "Delete 'any statistical assessment should include an evaluation of the dose response relationship'. This can turn out to be very problematic! No one has evaluated this, or its regulatory interpretation. Pair-wise tests have been evaluated and the relationship to SI=3 is largely understood; not so for D-R analyses."